Ethical question of the month — July 2002

A large amount of testing is required by veterinary pharmaceutical companies to license medications to treat specific diseases in specific species. The testing is required to demonstrate efficacy, safety, dosage, and withdrawal times, among other things. Licensed veterinarians, however, may prescribe medications in an extra-label manner (including changes to the indications, species, dosages, etc), based in their own understanding of pharmacology and disease pathogenesis. **Can veterinarians defend their right to prescribe in this manner?**

Question de déontologie du mois — juillet 2002

Les compagnies pharmaceutiques doivent effectuer de nombreux essais avant de pouvoir faire homologuer des médicaments pour le traitement de certaines maladies chez des espèces particulières. Ces essais portent notamment sur l'efficacité, l'innocuité, le dosage et le délai d'attente. Toutefois, les vétérinaires peuvent prescrire des médicaments en dérogation des indications fournies avec ces produits (écarts quant à la posologie, à l'espèce, au dosage, etc.) en s'appuyant sur leur connaissance de la pharmacologie et de la pathogenèse de la maladie à traiter. ***Les vétérinaires peuvent-ils justifier cette façon de prescrire des médicaments?***

An ethicist's commentary on extra-label drug use

Drug companies are driven by the need to produce profits for their stockholders. The cost of discovery and validation of new drugs for safety and efficacy is enormous, both in terms of money and time. For this reason, these companies are unwilling to make such an investment if a market big enough to justify the expenditures does not exist. While certain select veterinary drugs, such as ivermectin and carbrofen do create huge profits, many do not. The market for mouse analgesics, for example, is limited to research animals used in painful (usually surgical) protocols. Researchers with thousands of mice will not pay for expensive regimens. The market for tiger analgesics is considerably smaller, Food animal producers cannot pay $10 per daily dose for cutting edge antibiotics.

As of 1997, the number of companies doing animal health research on drugs in Canada had shrunk from 21 to 7. According to the Animal Health Institute in the United States, only 1 in 7500 compounds succeeds in gaining approval over a period of 10 to 12 years, at a cost of $250 000 000. Clearly drugs serving limited markets will not be forthcoming.

Veterinarians who wish to use only drugs approved for their particular species of interest thus face a huge obstacle; such drugs are rarely available. It is for this reason that legislatures have granted veterinarians the privilege of using drugs in an "off label" way; for example, in a manner that has not yet been approved for the species in question. Usually this means using human drugs in an animal species, but it may mean using a drug licensed for use in cattle in a pig or water buffalo, or licensed for use in dogs in a cat.

Such use is not just shooting in the dark. Safety and efficacy of human drugs are tested first in a number of animal species before clinical trials; if we can extrapolate from animals to humans, logic dictates that we can go in the other direction. In fact, when, in the mid-1980s, United States federal law mandated pain control for laboratory animals, such extrapolations were the basis for most analgesic use.

Furthermore, as we understand drug action in a clearer way, we can make reasonable extrapolations from established information. For example, we know that pain in pigs is not well-controlled by opiates, so the chances are that a new opiate will yield dubious results.

The point is that the alternative to extra-label drug use is doing nothing at all. The position of the Canadian Veterinary Medical Association (CVMA) on the extra-label use of drugs is to encourage Canadian veterinarians to prescribe veterinary approved drugs when available. The position states "the extra label use of drugs must be based on a valid veterinarian/client/patient relationship. Inherent with this is the responsibility to assure safe application to the animal and education of the client in a manner that will contribute to the safety and wholesomeness of foods of animal origin. Veterinarians can adhere to these principles through dedication to continuing education on pharmaceutical issues, and by obtaining the most up-to-date information from the pharmaceutical companies, veterinary colleges, and regulatory agencies" (1).

In the United States, the Animal Drug Use Clarification Act was passed in 1994. This law specifies that to use a drug in an off-label way, a veterinarian must have a valid veterinary/client relationship and not use the drug in animal feed. Certain drugs may not be used at all in food animals, for example, clenbuterol and chloramphenicol. Further, the Secretary of Health and Human Services may specify safe levels of residue for drugs used in food animals and require a method of detecting residues; proper labeling and record keeping are required by legislation based in 1997.

Some years ago, a number of veterinarians were cavalier about the use of antibiotics for growth promotion in feeds. This led Congress perilously close to banning extra-label drug use, which would have virtually destroyed veterinary medicine. Thus veterinarians should be careful not to violate the public trust in this area, lest a major tool be removed from them.

Ethical question of the month — October 2002

Responses to the case presented are welcome. Please limit your reply to approximately 50 words and mail along with your name and address to: **Ethical Choices, c/o Dr. Tim Blackwell, Veterinary Science, Ontario Ministry of Agriculture, Food and Rural Affairs, Wellington Place, R.R.#1, Fergus, Ontario N1M 2W3; telephone: (519) 846-3413; fax: (519) 846-8101. Suggested ethical questions of the month are also welcome! All ethical questions or scenarios in the ethics column are based on actual events, which are changed, including names, locations, species, etc., to protect the confidentiality of the parties involved.**

A veterinarian employed by a large integrated swine operation designs a clinical trial on the farm to test different prevention and treatment regimes for disease X. The results are very encouraging and the research is repeated in 3 subsequent trials on the farm with similar outcomes. Several months later with continued successful disease control, the veterinarian mentions in passing that she plans to report the results of this work at an upcoming veterinary meeting. The owner replies that he paid for all the costs of the work, including the veterinarian's wages, and, therefore, that he owns the results and is not interested in sharing this new and valuable information with his competitors. He refuses the veterinarian permission to report on the results of the trial to her colleagues. Does the owner have the right to stop the veterinarian from sharing this information with her colleagues?

Question de déontologie du mois — octobre 2002

Les réponses au cas présenté sont les bienvenues. Veuillez limiter votre réponse à environ 50 mots et nous la faire parvenir par la poste avec vos nom et adresse à l'adresse suivante : ***Choix déontologiques, a/s du Dr Tim Blackwell, Science vétérinaire, ministère de l'Agriculture, de l'Alimentation et des Affaires rurales de l'Ontario, R.R. 1, Fergus (Ontario) N1M 2W3; téléphone : (519) 846-3413; télécopieur : (519) 846-8101. Les propositions de questions déontologiques sont toujours bienvenues! Toutes les questions et situations présentées dans cette chronique s'inspirent d'événements réels dont nous modifions certains éléments, comme les noms, les endroits ou les espèces, pour protéger l'anonymat des personnes en cause.***

Une vétérinaire à l'emploi d'un important éleveur de porcs planifie des essais cliniques à la ferme afin de tester divers protocoles de prévention et de traitement de la maladie X. Les résultats sont très encourageants et, à trois reprises, les essais remportent le même succès. Quelques mois plus tard, le programme de prévention donnant toujours de bons résultats, la vétérinaire mentionne qu'elle a l'intention de présenter les résultats de cette recherche à l'occasion d'un prochain congrès de médecins vétérinaires. Le propriétaire lui répond qu'il a payé tous les coûts liés à la recherche, y compris le salaire de la vétérinaire, et que, par conséquent, les résultats lui appartiennent et qu'il n'est pas intéressé à donner cette précieuse information à ses concurrents. Il interdit à la vétérinaire de communiquer à ses collègues les résultats des essais. Le propriétaire a-t-il le droit d'empêcher la vétérinaire de communiquer cette information à ses collègues?